

Remarks

Claims 1-5, 8 and 10-13 were pending in the subject application. By this Amendment, the applicants have amended claims 1, 2 and 8. No new matter has been added by these amendments. Support for the amendments to the claims can be found throughout the original specification and claims as filed (see, for example, page 1, lines 30-31). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-5, 8, and 10-13 are before the Examiner for further consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicants wish to thank Examiner Srivastava and Supervisory Examiner Gitomer for the courtesy extended to the undersigned, and Mr. Robert Perry, during the personal Examiner Interview conducted on December 8, 2009. This Response and the amendments set forth herein are submitted in accordance with the substance of that interview and constitute a summary thereof.

Claim 2 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Office Action states that claim 2 is indefinite because the phrase "wherein the cell is immobilized on a magnetic particle" lacks sufficient antecedent basis because in claim 1 from which claim 2 depend the limitation is "immobilizing the cell on an antibody." By this amendment, the applicants have amended claim 2 to clarify that the antibody to which the cell is attached is, itself, attached to a magnetic particle.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under §112, second paragraph.

Claims 1-5 have been rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Bruno *et al.* (1996, *Applied and Environmental Microbiology* 62(9):3474-3476). The applicants respectfully traverse this ground for rejection because the cited reference does not teach or suggest the claimed method or device for detecting a cell's growth, metabolism, and/or germination based on changes in a holographic sensor.

In order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Bruno *et al.* disclose a method of measuring the number of spores in a sample liquid. The Bruno *et al.* method is selective for the spore by means of the antibody chosen. A culture is raised against the spores and antibodies isolated. Two antisera are then produced: one labeled with biotin and one with a reporter fluorescent label. The biotin-bearing antibody is attached to magnetic beads comprising attached streptavidin, and then dilutions of this are mixed with the liquid comprising the suspected spore. The reporter is then added to form a sandwich-type assay. Following vortexing to remove the unbound antibodies, the fluorescent count is read.

The Bruno *et al.* sensor is sensitive only to the presence of the spore through the reporter antibody, and not a change in metabolism, germination and/or growth of the cell in the device. The Bruno *et al.* assay will detect all spores in a sample whether dead or viable. Thus, it is not metabolism, growth and/or germination that cause the detection. The Bruno *et al.* device could not determine whether the spore is viable, which is an important advantage of the current invention. In contrast, the present invention is directed to detection of the metabolic activity, growth and/or germination of the cell, thus providing important information on the cell type and its viability.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known

elements in the fashion claimed” by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007).

Thus, the claimed method identifies and measures parameters that are different from those that are detected by Bruno *et al.* Furthermore, there are no teachings in the Bruno *et al.* reference that would provide the skilled artisan with any reason to modify the Bruno *et al.* methods to arrive at the current invention.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under §102(a) based on Bruno *et al.*

Claims 1-5, 8 and 10-13 have been rejected under 35 U.S.C. §103(a) as being obvious over Bruno *et al.* in view of Walt *et al.* (U.S. Patent No. 6,377,721), and Weimer *et al.* (U.S. Patent No. 6,399,317). The applicants respectfully traverse this ground for rejection because the cited references do not teach or suggest the claimed invention.

The shortcomings of the primary Bruno *et al.* reference, as that reference pertains to the current invention, have been discussed above. The Walt *et al.* and Weiner *et al.* references do not cure, or even address, the aforementioned shortcomings of the Bruno *et al.* reference.

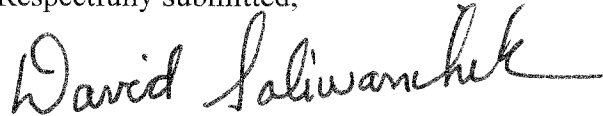
Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §103(a) based on Bruno *et al.* in view of Walt *et al.* and Weimer *et al.*

In view of the foregoing remarks and the amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik

Patent Attorney

Registration No. 31,794

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

DRS/la